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09/943,048	08/30/2001	Mawaheb M. EL-Naggar		8472

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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/943,048	Applicant(s) EL-NAGGAR ET AL.	
	Examiner Brian-Yong S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *2 and 3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 5* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, drawn to a method of treating tumor growth and metastasis.

II. Claim 3, drawn to a method of treating thromboembolic disorders.

III. Claims 4, drawn to a method of treating inflammatory disorders.

It is noted that claim 1 and 5 will be examined the extent to the group that is elected by the applicant since they contain common limitations for above groups I-III.

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions modes of operation, different functions, or different effects.

The above delineated invention are independent and patentably distinct each from the other. Each of the above groups is drawn to the treatment of totally different conditions and would appear to seek results which differ depending on what disease or conditions and would appear to seek results which differ depending on what disease or conditions is being treated.

One practicing the invention of any of the above groups would not necessarily be required to practice any of the others. Further a reference which anticipates the invention of one of the above groups would neither anticipate or make obvious any of the other inventions. The search for above inventions would not be co-extensive, particularly as to the literature search required. Clearly each of the above inventions is capable of supporting it's own patent. Therefore restriction for examination purpose is proper.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. During a telephone conversation with Mawaheb M. EL-Naggar on March 26, 2002 a provisional election was made to prosecute the invention of III, claim 4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2 and 3 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

4. Claim 5 is objected to because of the following informalities:

5. Claim 5 should begin with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviation. *See Fressola v. Manbeck, 26 USPQ2d 1211 (.D.C. 1995)*. Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i). Appropriate correction is required.

6. Claim 5 is also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is unclear and vague what is meant by "treating inflammatory" and the specification does not define the term. Although the term "treating inflammatory" itself appears to be definite, "treating inflammatory" is inconsistent with specification disclosure which is directed to a treatment of inflammatory and thrombotic disorders (page 4, lines 9-15) and thereby making an otherwise definite claim take on an unreasonable degree of uncertainty.

Additionally, Claim 1 is unclear and vague by reciting "other specific COX2 inhibitors" and the specification fails to define the term. What are "other specific COX2 inhibitors"?

8. Claim 4 is unclear and vague by reciting "as defined earlier in the background". Although the specification discloses various diseases that is related to inflammatory and thrombotic disorders (page 4, lines 9-15), the claims themselves must to point out the claimed invention with the reasonable clarity and precision. In other words, where possible, claims are to be complete in themselves. Incorporation by reference to a specific disclosure, for example, figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).*

Applicant is requested to amend Claims 3-4 with proper Markush-type language format.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (US 6306842 B1) in view of Ares et al. (US 5399584), or if necessary further in view of Anderson et al. (US 6248341 B1).

The claims read on a method of treating inflammatory disorders with a combination of COX2 inhibitors, low dose aspirin and flavonoids or isoflavones.

Lai et al teaches the combination use of NSAID such as aspirin and COX-2 inhibitors for treating inflammatory disorders (claims 2-5 and 20).

Ares et al teaches the use of flavonoids for treating damage to the mucosal lining of the gastrointestinal tract (e.g., gastrointestinal ulcer) caused by NSAID (abstract, column 3, lines 16-30 and lines 46-65).

Anderson et al teaches the use of flavonoids such as epigallocatechin-gallate, epicatechin gallate for treating inflammatory disease (column 2, lines 51-53).

The teaching of Lai differs from the claimed invention in 1) the use of flavonoids or isoflavones in combination with aspirin and COX2 inhibitors and 2) use of low dose aspirin. To incorporate such teaching into the teaching of Lai, would have been obvious in view of Ares who teaches the use of flavonoids or flavones for treating damage to the mucosal lining of gastrointestinal tract caused by NSAID. One having ordinary skill in the art would have motivated to modify the teaching of Lai such that gastrointestinal side effects associated with NSAID such as aspirin (column 1, lines 19-22 of Lai'842; column 1, lines 14-26 of Ares'584) would be greatly reduced.

Alternatively, the above references in combination make clear that COX2 inhibitors, aspirin and flavonoids have been individually used for the treatment of inflammatory disorders. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught